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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,636	09/04/2007	Neil L. Anderson	559022000300	4373

25226 7590 12/22/2010

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EXAMINER	
CARDINAL, ERIN M	

ART UNIT	PAPER NUMBER
4136	

NOTIFICATION DATE	DELIVERY MODE
12/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,636	ANDERSON ET AL.	
	Examiner	Art Unit	
	Erin M. Cardinal	4136	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *25-MAY-06, 18-APR-07, 21-MAR-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 9 and 11 are objected to because of the following informalities:

   a. claim 9 as amended is not grammatically correct; the examiner suggests deleting the word "in" and the comma after "disposable" and

   b. claim 11 appears to repeat the phrase "the distal end" in the last line; for analysis the entire phrase is interpreted to mean the most distal end of the tubular member.

   Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the steering mechanism" in the last line of the claim. For analysis, "the steering mechanism" is interpreted as "the shape-imparting mechanism."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,514,131 A to Edwards et al. (hereinafter "Edwards").

6. Regarding claim 1, Edwards discloses a modular catheter (Figs. 9, 10, 13 and 17). An elongate tubular member (92) has a proximal end (94) and a closed distal end (96) with a lumen extending from the proximal end to the distal end (Fig. 10) and a plurality of electrodes (124, including bipolar configurations) arranged at, or adjacent, the distal end (Fig. 10). Conductors for the electrodes are contained within a wall of the tubular member (Fig. 10, all distal components are inside the walls of the tubular member). An elongate shape-imparting mechanism (116/118/120 and 122; wires 116, 118, and 120 steer the catheter and sleeve 122 changes its length) is removably received within the lumen of the tubular member such that a distal end of the shape-imparting mechanism is substantially in register with the distal end of the tubular member (Fig. 10). A control device (90) has a proximal end and a distal end (Fig. 9). The proximal end (94) of the tubular member (92) and a proximal end of the shape-imparting mechanism (116/118/120 and 122) are releasably connectable (col. 6, lines 24-27 and col. 7, lines 44-58) to the distal end of the control device (116/118/120 are connected to controls 102 and 104 within control device 90 and 122 is connected to control 26; see Fig. 17, col. 6 line 65 to col. 7 line 4).

7. Regarding claims 2-5, Edwards discloses that the shape-imparting mechanism (116/118/120 and 124) and the tubular member (92) are releasably connectable to the control device (90) independently of each other (Figs. 9 and 17, col. 7 line 44 to col. 8 line 3). The shape-imparting mechanism (122) has an outer diameter approximating that of a diameter of the lumen of the tubular member (92) to be a snug fit within the lumen of the tubular member (Fig. 10). The shape-imparting mechanism (116/118/120) also comprises a steering mechanism to effect steering of the distal end of the tubular member (col. 6, line 65 to col. 7 line 14). The proximal end (94) of the tubular member (92) carries a connector thereon for connection to a corresponding connector of the control device (col. 6, lines 19-21).

8. Regarding claims 6-8, Edwards discloses a proximal end of the shape-imparting mechanism (length shaping sleeve 122) carries a coupling mechanism (the end shown in Fig. 17 that connects to 152) for effecting releasable mechanical coupling (Fig. 17 shows the coupling released) to the control device (90) and to a manipulating element (26) of the control device (Fig. 17). The manipulating element (26) is an actuator which is linearly displaceable relative to a body of the control device (Fig. 4, col. 5 lines 26-39 and col. 6 lines 21-22). The coupling mechanism (Fig. 17) has a first securing formation releasably connectable to the body of the control device (hinge 110 on the control device 90 releases surface 109, moving the connector 152 and contact 148) and a second securing formation releasably connectable (the end of length shaping sleeve 122 shown in Fig. 17 is connected to 152) to the actuator (26) so that displacement of the securing formations relative to each other (moving 26 laterally within 109) causes

lateral displacement of the distal end of the shape imparting mechanism (it slides laterally along the electrode) and, hence, the distal end of the tubular member (the distal end of the tubular member effectively retracts; see e.g. Fig. 7 and Figs. 9-10).

9. Regarding claim 10, Edwards discloses the shape-imparting mechanism includes a stylet (122) which is received in the lumen of the tubular member (Fig. 17).

10. Regarding claim 11, Edwards discloses a modular catheter (Figs. 9, 10, 13 and 17). An elongate tubular member (92) has a proximal end (94) and a closed distal end (96) with a lumen extending from the proximal end to the distal end (Fig. 10). A plurality of electrodes (124, including bipolar configurations) are arranged at, or adjacent, the distal end (Fig. 10) and conductors for the electrodes are contained within a wall of the tubular member (Fig. 10, all distal components are inside the walls of the tubular member). An elongate shape-imparting mechanism (122) is removably received within the lumen of the tubular member such that a distal end of the shape-imparting mechanism is substantially in register with the distal end of the tubular member (Fig. 10). An elongate control device (90) has a proximal end and a distal end (Fig. 9). The proximal end (94) of the tubular member (92) and a proximal end of the shape-imparting mechanism (122) are releasably connectable (col. 6, lines 24-27) to the distal end of the control device (Fig. 17) and the control device (90) carries an actuator thereon (26) which is displaceable along a longitudinal axis of the control device (Fig. 4, col. 5 lines 26-39 and col. 6 lines 21-22) for controlling displacement of the distal end of the shape-imparting mechanism to effect displacement of the distal end of the tubular member (see Fig. 7 and Figs. 9-10).

11. Regarding claim 12, Edwards discloses a modular catheter (Figs. 9, 10, 13 and 17). An elongate tubular member (92) has a proximal end (94) and a closed distal end (96) with a lumen extending from the proximal end to the distal end (Fig. 10). A plurality of electrodes (124, including bipolar configurations) is arranged at, or adjacent, the distal end (Fig. 10) and conductors for the electrodes are contained within a wall of the tubular member (Fig. 10, all distal components are inside the walls of the tubular member). An elongate shape-imparting mechanism (122) is removably received within the lumen of the tubular member such that a distal end of the shape-imparting mechanism is substantially in register with the distal end of the tubular member (Fig. 10). A control device (90) has a proximal end and a distal end (Fig. 9) The proximal end (94) of the tubular member (92) and a proximal end of the shape-imparting mechanism (122) are releasably connectable (col. 6, lines 24-27) to the distal end of the control device (Fig. 17). The control device includes a body (90) and an actuator (26) displaceably arranged on the body (Figs. 4 and 9). A proximal end of the shape-imparting mechanism (Fig. 17) carries a first securing formation (the end of 122) releasably connectable to the actuator (152 and 26) and a second securing formation (the end of electrode 124 is carried by 122) releasably connectable to the body (from the end of 124 through connector 150 and 24 to the body 90).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,924,977 A to Yabe et al. (hereinafter "Yabe"). Edwards discloses the limitations of the claimed invention as described above in paragraph 6, except for a disposable covering member for the control device. Yabe teaches surgical instrument handles with disposable covers (22, Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the catheter of Edwards with the instrument handle cover of Yabe to make the device cleaner and easier to sterilize after use, as taught by Yabe in col. 2, lines 18-46.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,007,531 to Snoke et al. teaches a steerable catheter with modular or disposable distal components.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erin M. Cardinal whose telephone number is 571-270-3148. The examiner can normally be reached on Monday through Thursday 7:30 AM - 6:00 PM EST.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

/E. M. C./
Examiner, Art Unit 4136